

EXPRESS MAIL NUMBER:

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Doherty et al.

Filing Date: 16 February 2000

Serial No.: 09/506,079

5 For: HER-2 BINDING ANTAGONISTS

Art Unit: 1642

Examiner: Anne L. Holleran

Docket: 49321-16

Date: 19 April 2003

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Mail Stop AF Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

15 **AFFIDAVIT OF DR. GAIL M. CLINTON UNDER 37 C.F.R. § 1.132**  
(IN SUPPORT OF RESPONSE AND AMENDMENT UNDER 37 CFR § 1.116)

Sir or Madam:

I, Dr. Gail Clinton, being duly sworn, say:

20 1. I am an inventor of the subject matter described in the above-identified pending patent application.

2. I am an internationally recognized scientist and am presently employed as an Associate Professor at Oregon Health and Sciences University in Portland, Oregon (from 1/01/87 to present). I received a Bachelor of Science Degree in 1969 from the University of California, San Diego, and a Ph.D. degree from the University of California, San Diego in 1974. I completed a postdoctoral fellowship at Harvard Medical School in 1981.

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3. I am an author or co-author of more than 45 peer-reviewed research articles and I am a member of a number of scientific and medical societies, most notably American Association of Cancer Research. I have received a number of prizes and awards for achievement

in research, most notably I was the recipient of a distinguished postdoctoral fellowship from the American Cancer Society, numerous grants from the National Cancer Institute, and was awarded a Fogarty Senior International Fellowship. I have served on several peer review groups and study sections and have been invited to give numerous presentations on my research at national and international meetings.

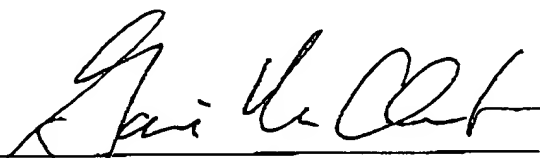
4. I have read the above-identified patent application, and the attached Response and Amendment, and it has been explained to me that particular claims have been rejected according to the Patent Examiner for introducing *new matter* by prosecution amendment, in each case based on an alleged lack of written description to support the exclusion of polypeptides corresponding to SEQ ID NOS:11 and 12 (and fragments of these) from the originally claimed subject matter. In more simple terms, I understand that the Examiner is questioning whether patent claims to the variants, apart from the Herstatin that was previously disclosed and claimed, was actually appreciated at the time this application was filed. It most definitely was.

5. The discovery of these novel polymorphisms was precisely the reason that the present application was filed. The Herstatin sequence of the earlier U.S. patent application (09/234,208) was already disclosed and claimed in that application, and it was the primary purpose of the present application to claim additional polymorphisms, while not claiming the previously claimed Herstatin. In Example 11 of the present application, the 1999 Doherty et al. PNAS paper (which lists the previously claimed Herstatin) was cited in the introduction. Example 11 then goes on to describe the additional, different polymorphisms by their nucleotide and deduced amino acid sequence. These additional variations in the intron-8 encoded domain were discovered in the human population and Table 1 sets forth those variants, including originally identified variant 11. Said another way, while Table 1 of Example 11 lists the Doherty et al sequence as variant 11 along with the additional polymorphisms (variants 1-10), the purpose of the table is to set forth and summarize additional variants of the intron-8 encoded domain that had been discovered to the time of the filing of this patent application.

6. In conclusion, the discovery of several variations in the intron-8-encoded portion of Herstatin led to the filing of this patent application describing and claiming those Herstatin

polymorphisms, excluding Herstatin set forth in SEQ ID NOS:11 and 12.


7. I further declare that all statements made herein of my own knowledge are true and that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

  
Gail M. Clinton



10 State of Oregon )  
County of Multnomah ) ss.:

15 On this <sup>21<sup>st</sup></sup> ~~19<sup>th</sup>~~ day of April, 2004, before me, a Notary Public in and for the State and County aforesaid, personally appeared Gail M. Clinton, to me known and known to me to be the person of that name, who signed and sealed the foregoing instrument, and he acknowledged the same to be her free act and deed.

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Notary Public

Commission expires August 28, 2005